A combined physical exercise and psychosocial training program to improve physical fitness in children with cancer.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON38397

Source
ToetsingOnline

Brief title
QLIM: Quality of Life In Motion

Condition

- Bone disorders (excl congenital and fractures)
- Miscellaneous and site unspecified neoplasms benign
- Changes in physical activity

Synonym
Childhood cancer and reduced physical fitness

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Roparun;Alpe d'HuZes/KWF

Intervention

Keyword: Body composition, Childhood cancer, Health-related quality of life, Physical fitness

Outcome measures

Primary outcome

The primary outcome of the study is physical fitness (both cardiorespiratory

fitness and muscle strength).

Secondary outcome

Secondary outcomes will be:

- fatigue

- body composition

- daily physical activity levels

- depression

- Health-related quality of life (HrQOL)

- self perception and behavior.

Additional:

- compliance and satisfaction with the intervention

- Potential moderating variables, including pre-illness lifestyle, and health-

and exercise-related attitudes, beliefs and motivations of both children and

parents.

Study description

Background summary

Advances in diagnosis and treatment of childhood cancer have dramatically increased long-term survival. As a result, the numbers of childhood cancer survivors (CCS) are growing. A recent study has shown that approximately 75% of CCS have at least one adverse health effect after a median follow-up of 17 years. Prevention or reduction of acute and long-term adverse health effects should be pursued in order to maintain or improve health-related quality of life (HrQOL). Physical fitness has been shown to be reduced both during and after childhood cancer with physical inactivity being one of the most prominent causes. Physical inactivity may lead to obesity, fatigue, a poor skeletal and/or mental health, and ultimately a compromised HrQOL. Therefore, prevention of inactivity-related health problems by increasing physical fitness both during and following treatment is essential. Rehabilitation programs in adult cancer patients report positive effects on physical fitness and HrQOL and have been introduced as standard care. However, such a program does not exist for childhood cancer patients (CCP). Limited evidence suggests that it is safe for CCP to engage in physical activities and that physical exercise programs are capable of increasing physical fitness both during and following treatment. However, study groups were small, restricted to children with acute lymphoblastic leukemia, and effects on health outcomes and HrQOL were rarely assessed. In addition, the interventions included a physical exercise program only, thus not addressing the psychosocial factors affecting physical activity in CCP.

Study objective

The proposed study is part of a larger KWF program proposal: the Alpe d*HuZes Cancer Rehabilitation Research Program (A-CaRe) coordinated by the EMGO Institute. The aim of the study is to evaluate the short- and long-term effectiveness of a combined physical exercise and psychosocial intervention program, implemented during or shortly after treatment, in improving the physical fitness of CCP. In addition, it will be determined whether positive effects on physical fitness will attenuate or even prevent inactivity-related health problems (i.e. fatigue, obesity) and improve HrQOL.

Study design

The proposed study is a multi-centre randomized clinical trial.

In total, 100 consenting patients will be randomized to either the intervention or the control group after being stratified according to type of malignancy, age group, and moment of inclusion into the study (during/after treatment).

Randomization will occur as soon as the clinical condition of the patient enables him/her to participate in and complete the intervention program.

All patients will be asked to undergo performance tests (Cardiorespiratory fitness: peak oxygen consumption (VO2-peak), peak work load (Wmax) and peak heart rate; muscle strength: arms and legs - both left and right side of the body) and are asked to undergo tests for health examination (1) DEXA scan: both lumbar spine as full body; 2) Blood: magnesium, phosphate, calcium, 1CTP, PTH, P1NP, IGF-1, 25 OH vit D; 3) pulmonary function: FEV1 and FEVC; 4) electrocardiogram; 5) blood pressure) and complete a battery of questionnaires. These measurements occur prior to randomization (T=0), after 12-14 weeks (T=1) and at 12 month follow-up (T=3). At T=2 (6-9 months from baseline) only the questionnaires will be administered.

Intervention

The 12-week intervention consists of a combined physical exercise (2x/week) and psychosocial training program followed by an one day booster session. The physical exercise program includes both cardiorespiratory and muscle strength training, and the psychosocial training program (6 child and 2 parent sessions) contains psycho-education and cognitive-behavioral therapy.

The control group will receive care as usual.

Study burden and risks

Burden
This study will be measured on 3 occasions with a 12 months period. Measurements include all primary and secundary outcome measures. An additional measurement will be performed in approximatly in the seventh month following the start of the study. This measurement includes measurments of questionnaires only.

Measurments of all primary and secundary outcome measures will occur within a 5,5 hours period. This provides the children with ample apportunity to recover between the different tests.

Risks
Risks accompanying DEXA scans and blood sampling are minimal. The amount of radiation during a DEXA scan is equivalent to a persons normal daily environmental radiation dose. To reduce the number of vena-punctions and associated burden, blood sampling for research will be recommended with blood sampling for "usual care" as much as possible. This will also reduce a possible risk for infections. When available, a central venous access devise will be used to collect blood.

Risks associated with the intervention are limited. Recent study has shown that children during cancer treatment are well able to perform physical exercise. However, due to a decreased bone mineral density during diagnosis and the intensive fase of the treatment of Acute Lymphoblastic Leukemia (ALL) there may be an increased risk for bone fractures. To decrease this possible bone fracture risk, the intensity of the program will slowly increases, sports that include body contact (judo or rugby) will not be performed, the physical intervention program is individualist and patients are monitored repeatedly during the training.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children treated with chemotherapy and/or radiotherapy.

Exclusion criteria

Age: younger than eight years old

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	28-01-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2012
Application type:	Amendment

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL23916.029.08
Other	TC 1531